

comprises an outer sheath comprising an elongated tubular body and a distal section. The distal section is formed from a light transmissive material whereby the stent may be visually inspected through the distal section.

Claim 1 points out how the distal section is an enlarged distal section and that there is an inner shaft located coaxially within the outer sheath; that a self-expanding stent is located within the relatively clear distal section of the outer sheath, that the stent makes frictional contact with the outer sheath and that the shaft is connected to the stent for delivery of the stent.

Claim 6 brings out how the proximal end of the distal section is bonded to the distal end of the tubular body member. Claim 10 also brings out how a flexible distal tubular section is bonded to the polymeric tubular body member and that the distal tip comprises a polymeric formulation containing from about 20 to 75 weight percent of a polymeric radiopaque agent to be substantially more radiopaque than the distal tubular section and the tubular body member of the sheath. Claim 12 brings out that the distal section is enlarged and that the proximal end of the enlarged distal section is bonded to the distal end of the tubular body member.

New claim 17 brings out that the sheath comprises an inner Teflon layer having stainless steel braiding disposed thereon, with a coating applied over and bonded to the braiding with a coating of the distal section being formed from a light transmissive material.


The Examiner has rejected claims 1, 6, 9, and 12 as unpatentable over Diaz U.S. Patent No. 6,379,365 in view of the Sullivan PCT Publication WO98/23241 and some of the claims as unpatentable over Diaz and Sullivan in view of Willard U.S. Patent No.

6,309,379. First, Diaz is irrelevant to the present invention because Diaz does not concern a self-expanding stent. In sharp contrast, Diaz concerns a balloon expandable stent which operates in a manner that is completely different from the self-expanding stent of the present invention. Still further, Diaz cannot be applied as a prior art reference against the present claims because Diaz qualifies as prior art only under 35 U.S.C. § 102(e) and at the time the present invention was made, Diaz was subject to an obligation of assignment to Cordis Corporation, the assignee of the present invention. See MPEP ¶ 715.01(b). Attached as Exhibit 1 to this Amendment, is a copy of Mr. Diaz's employment agreement and Exhibit 2 is a copy of Mr. Diaz's invention record, these exhibits showing that the invention of the Diaz patent was subject to an obligation of assignment to Cordis Corporation, the assignee of the present application.

With respect to the Sullivan PCT Publication, it is noted that Sullivan does not disclose an enlarged distal section, nor does Sullivan disclose a proximal end of the distal section being bonded to the distal end of the tubular body member, nor does Sullivan disclose a distal tip containing from about 20 to 75 weight percent of a polymeric radiopaque agent to be substantially more radiopaque than the distal tubular section and a tubular body member, nor does Sullivan disclose an inner Teflon layer having stainless steel braiding disposed thereon.

In view of the foregoing, it is submitted that the application is now in condition for allowance and an early Notice of Allowance is respectfully requested.

Respectfully submitted,
SEYFARTH SHAW

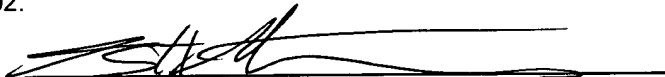


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Attorney for Applicant

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Honorable Commissioner of Patents and Trademarks, Washington, D.C. 20231 on December 13, 2002.



Registered Attorney for Applicant
Date: December 13, 2002

CH1 10460600.1

**CONFIDENTIAL INFORMATION AND PATENT AGREEMENT
(NON-EXEMPT)**

Cordis

Last Name (Print) DIAZ First Name ALEX Initial _____
Social Security No. _____ Dept. No. 6656

The medical device fields in which Cordis Corporation ("Cordis") is active are technologically intensive and highly competitive. Success in these fields requires the cooperation and interaction of employees with skills, knowledge and expertise in various technical areas. Such cooperation involves the access to and discussion of many kinds of valuable, confidential and proprietary information such as product development plans, engineering specifications, manufacturing techniques and equipment, schematics, product performance data, customer lists, and marketing plans. In order to further your professional goals and enhance Cordis' performance in the medical industry, Cordis will provide you with access to the proprietary and confidential information necessary for you to perform your duties in an effective and professional manner.

In consideration of employment by Cordis and in consideration of the salary or wages received by you during such employment, you hereby agree as follows:

1. That you will not disclose to anyone, other than those persons normally furnished such information in the course of Cordis' business, any confidential information relative to the business, sales, customers, products, training methods, product development plans, or financial condition of Cordis, whether developed by you or others, without the written consent of a Cordis Corporation Officer. You acknowledge that such information is highly confidential and proprietary information which Cordis keeps secret and does not disclose to the general public.
2. That upon termination of employment with Cordis, you will not take or keep any documents or materials including but not limited to, papers, publications, customer lists, brochures, catalogs, training manuals, design plans, engineering drawings, specifications, files, equipment, samples, credit cards, computerized data, or any original documents or copies of any kind, however formal or informal, belonging to, furnished by or relating to Cordis, including documents and materials generated in whole or in part by you during the term of your employment.
3. That all inventions and discoveries made by you, solely or jointly with others, during the period of your employment by Cordis and six months thereafter, arising out of your employment or pertaining to the business or the research activities of Cordis, and all records and reports including original notebooks, drawings and memorandums, are and shall be property of Cordis.
4. That you will promptly, without request, disclose to Cordis all such inventions and discoveries made by you.
5. That, upon request of Cordis, and at its expense, you will apply for Letters of Patent in this and in foreign countries on such inventions and discoveries and will execute all papers necessary thereto, including assignments of patent applications and patents.
6. That this agreement, and all provisions herein, shall be severally and collectively construed and governed in accordance with the laws of the state of Florida.
7. That the undersigned has read this Agreement carefully, understands its content and has chosen to sign the Agreement freely and voluntarily.



Employee Signature <u>[Signature]</u>	Date <u>2/2/97</u>	Human Resources <u>[Signature]</u>	Date <u>2/2/97</u>
Witness Name (Print) <u>DAVID G. GORRUCH</u>	Date <u>2/2/97</u>	Witness Signature <u>[Signature]</u>	Date <u>2/3/97</u>

no-agreement/CN5-13-91

Pat. Dept. *ml*
DEC 16 1997

Cordis

INVENTION DISCLOSURE FORM

No. 1019.304

DESCRIPTIVE TITLE: **LOW PROFILE SHEATHED STENT DELIVERY SYSTEM**

- I. **INSTRUCTIONS:** This form should be typed, except for signatures and dates. Disclose only one invention on this Invention Disclosure form, and complete the entire form as fully as possible. Forward the completed form to the Legal Department, signed and dated by all inventors and two witnesses. Refer to this Invention Disclosure by the number assigned to it when receipt is acknowledged. Attach additional sheets if more space is required.
Each original piece of paper and all attachments, including separate drawings pasted to a sheet, must be signed and dated by every inventor and by each witness. If a separate drawing is attached, please copy the sheet and attachments before signing the copy.
- II. **ILLUSTRATION:** Include a drawing, sketch, photograph, flow chart, or preferably an engineering quality printout of the invention. If a separate drawing is attached to this sheet, then this sheet and the attached drawing must be signed and dated separately.

SEE ATTACHED DRAWINGS

EXHIBIT

2

Signature of Inventor(s):
Date: 12/11/97



Date:

Witnesses:

Kevin Milra 12/10/97
Pat. [Signature] 12-11-97

Pat. Dept.
DEC 16 1997

III. EXPLANATION OF INVENTION: Describe the invention completely, including all essential elements.

THE SYSTEM IS COMPOSED OF A BALLOON CATHETER, A SHEATH AND A CONED FLEXIBLE TIP. THE BALLOON CATHETER IS MADE WITH A CHANNELED SHAFT. THE CHANNEL IS MADE TO ACCOMMODATE THE GUIDE WIRE. THE SHAFT IS DIVIDED INTO TWO SECTIONS, THE INFLATION LUMEN AND THE GUIDE WIRE CHANNEL (REFERENCE DRAWING 2A). CONNECTED TO THE DISTAL END OF THE CHANNEL SHAFT IS A BALLOON ASSEMBLY. THE PROXIMAL END OF THE SHAFT HAS A BALLOON HUB ASSEMBLY.

THE CONFIGURATION FOR THE BALLOON ASSEMBLY IS SHOWN IN FIGURES 1A AND 1B. NOTE IN FIGURE 1B ILLUSTRATES THE CONED FLEXIBLE TIP.

THE SHEATH SURROUNDS THE BALLOON ASSEMBLY AND SHAFT OF THE BALLOON CATHETER. THE DISTAL END OF THE SHEATH CONNECTS WITH THE CONE SHAPED FLEXIBLE TIP.

IV. NOVEL FEATURES AND ADVANTAGES: What is new that was not previously known, and why is this important.

THIS DESIGN MAXIMIZES INFLATION LUMEN BY PARTIALLY ENCLOSING GUIDE WIRE INSIDE A CHANNEL, ALLOWING MORE AREA FOR INFLATION LUMEN. CONSEQUENTLY IMPROVED BALLOON INFLATION / DEFLATION TIMES EXPECTED (TO DECREASE).

THE SHEATH WILL BE RESPONSIBLE FOR MAINTAINING THE GUIDE WIRE INSIDE THE CHANNEL AT ALL TIMES.

THIS DESIGN WILL OPTIMIZE THRU LUMENS ALLOWING THE SUBSTANTIAL DECREASE IN THE OVERALL SYSTEM PROFILE DIMENSIONS.

V. MODIFICATIONS: Describe all possible modifications or alternate embodiment

N/A

VI. RELATED DOCUMENTS: List all known relevant art references (patents, publications, commercially available products, etc.) Please supply copies of the documents, if available.

DISCLOSURE OF NOVEMBER 1997 "HIGH VISIBILITY SDS BY CHIP BEVIER/CEŠAR SILVA

Signature of Inventor(s):

Date:

12/11/97



Date:

Witnesses:

CEŠAR SILVA 12/10/97

Chip Bevier 12-11-97

Pat. Dec 16 1997

VII. INVENTORS:

First Inventor's Full Name (Please type):

ALEXIS DIAZ

Signature:

Date:

Second Inventor's Full Name (Please type):

Signature:

Date:

VIII. WITNESSES: This invention was disclosed to and understood by:

Full Name of First Witness (Please type):

CESAR SILVA

Signature:

Date: 12/10/97

Full Name of Second Witness (Please type):

PETER PIFERI

Signature:

Date: 12-11-97

Signature of Inventor(s):

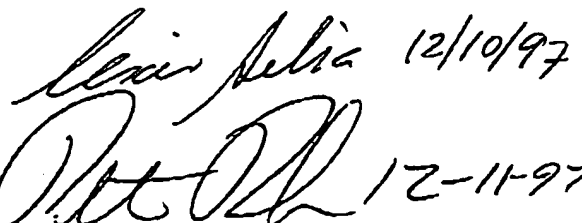
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Date:

12/11/97



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IX. ADDITIONAL INFORMATION:

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DEC 16. 1997/A

Invention is recorded on page(s): N/A
dated: N/A

of Notebook

where

Earliest date: 12/3/97 and place: 7H R AND D LAB
inventors first thought of the present invention.

First written description (date and present location):
12/3/97 R AND D LAB

First sketch of the invention (date and present location):
12/3/97 R AND D LAB

Earliest date: N/A and place: N/A where first operating model was
completed.

Present location of model:
N/A

Earliest date of use of the invention (actual or contemplated):
N/A

Earliest shipping date (actual or contemplated): N/A

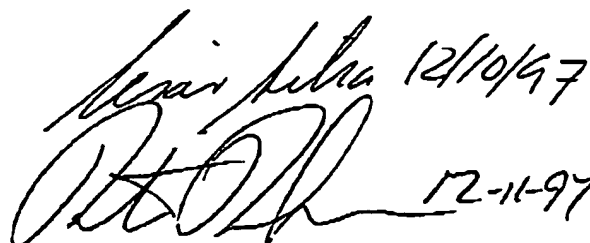
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Date:

Witnesses:


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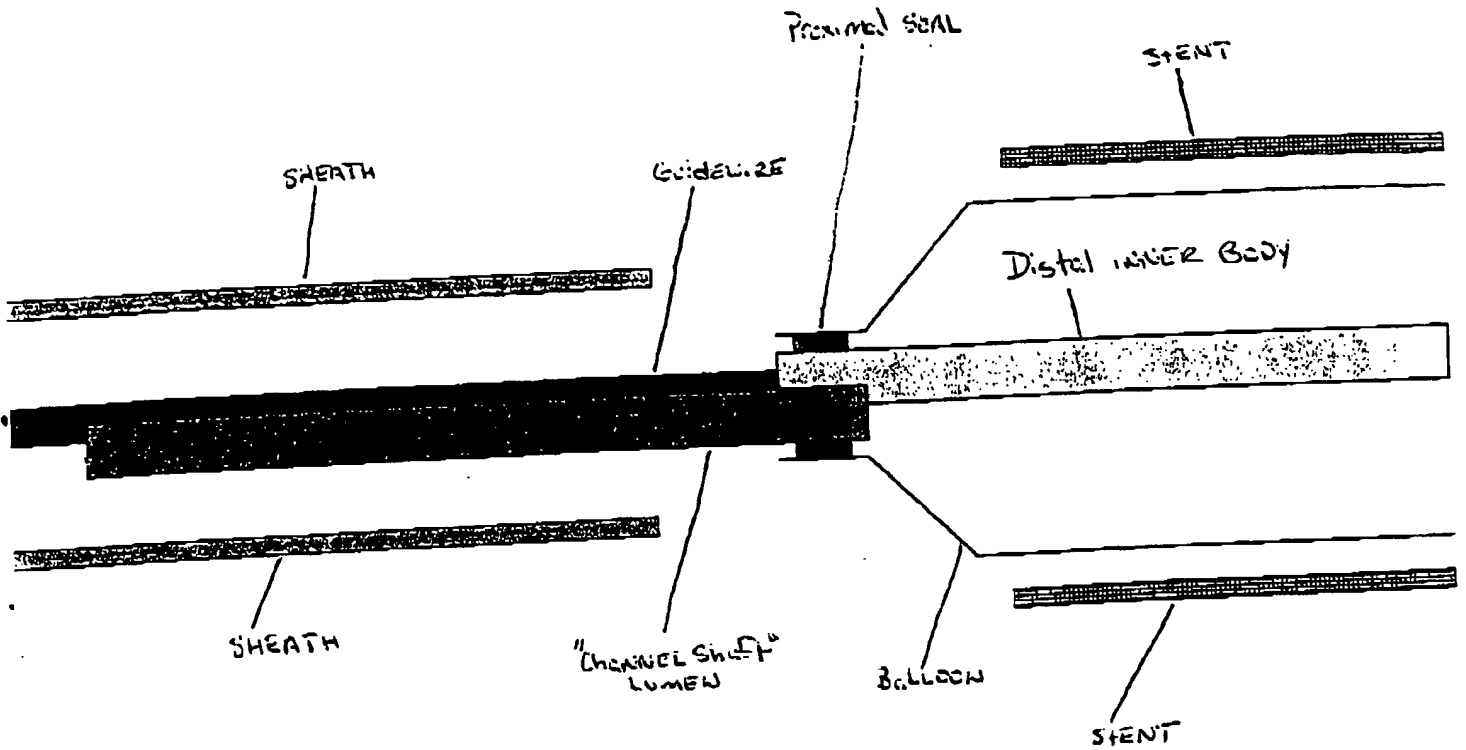
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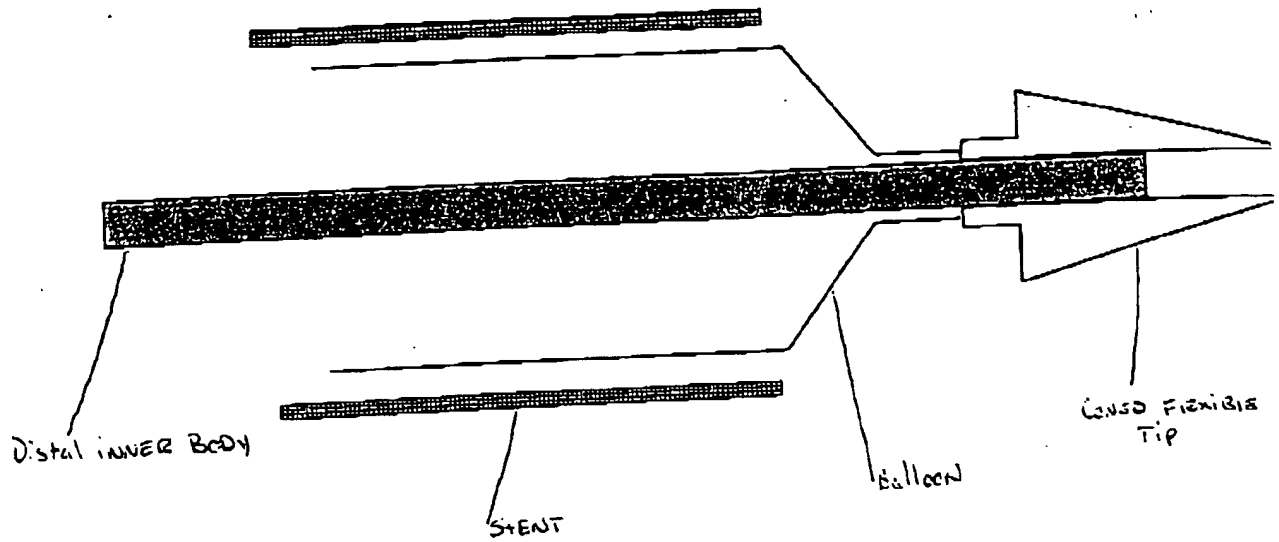
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Leslie J. [unclear] 12/10/97
[Signature] 12-11-97

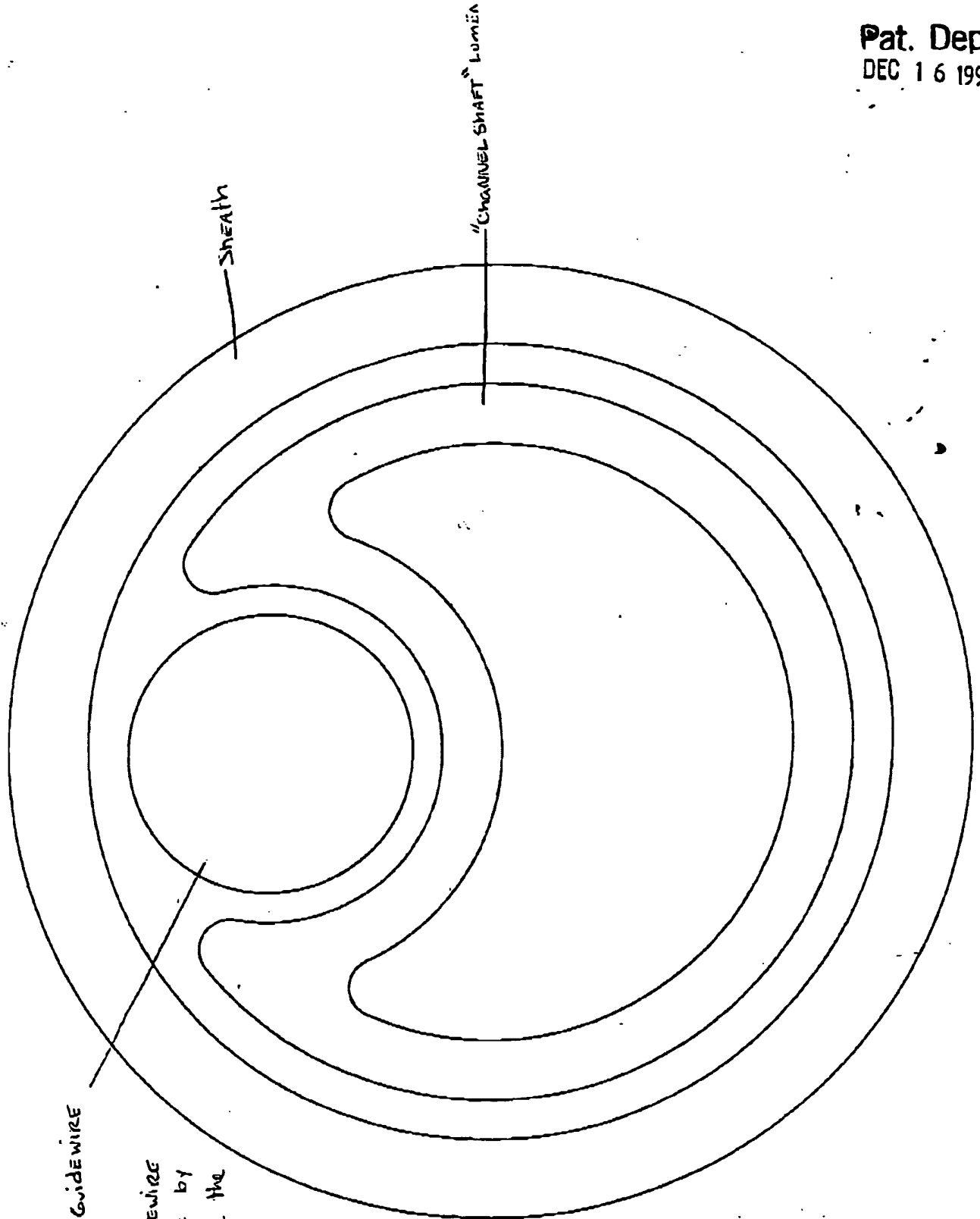
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[Signature] 12-11-97

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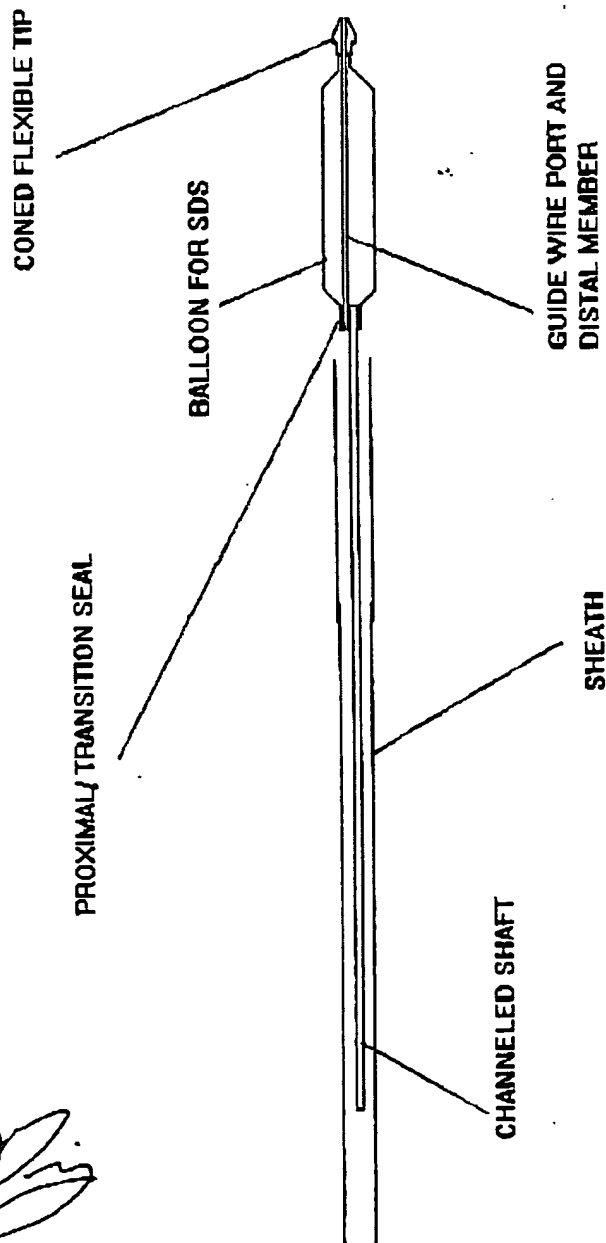
GUIDEWIRE

* NOTE THE GUIDEWIRE
IS ONLY IN PLACE BY
THE CHANNEL AND THE
SHEATH.

[Signature]
12/10/97

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12-11-97

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DEC 16 1997



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[Signature] 12-11-97